"CBER 101"

FDA Advisory Committees and Consultants

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CBER

March 25, 2003

Advisory Committee Philosophy

"The best sound basis for wise regulatory decisions is good scientific evidence and the thoughtful advice of public spirited experts who have taken the time to study, listen, learn the issues and provide recommendations without unreasonable prejudice."

FDA Has a Total of 33 Advisory Committees Which Service the Commissioner's Office and the Following Centers:

- Center for Biologics Evaluation and Research
- Center for Drug Evaluation and Research
- Center for Devices and Radiological Health
- Center for Food Safety and Nutrition
- Center for Veterinary Medicine

CBER's Five Advisory Committees

- Allergenic Products
- Biological Response Modifiers
- Blood Products
- Vaccines and Related Biological Products
- Transmissible Spongiform Encephalopathies

Composition of Advisory Committees

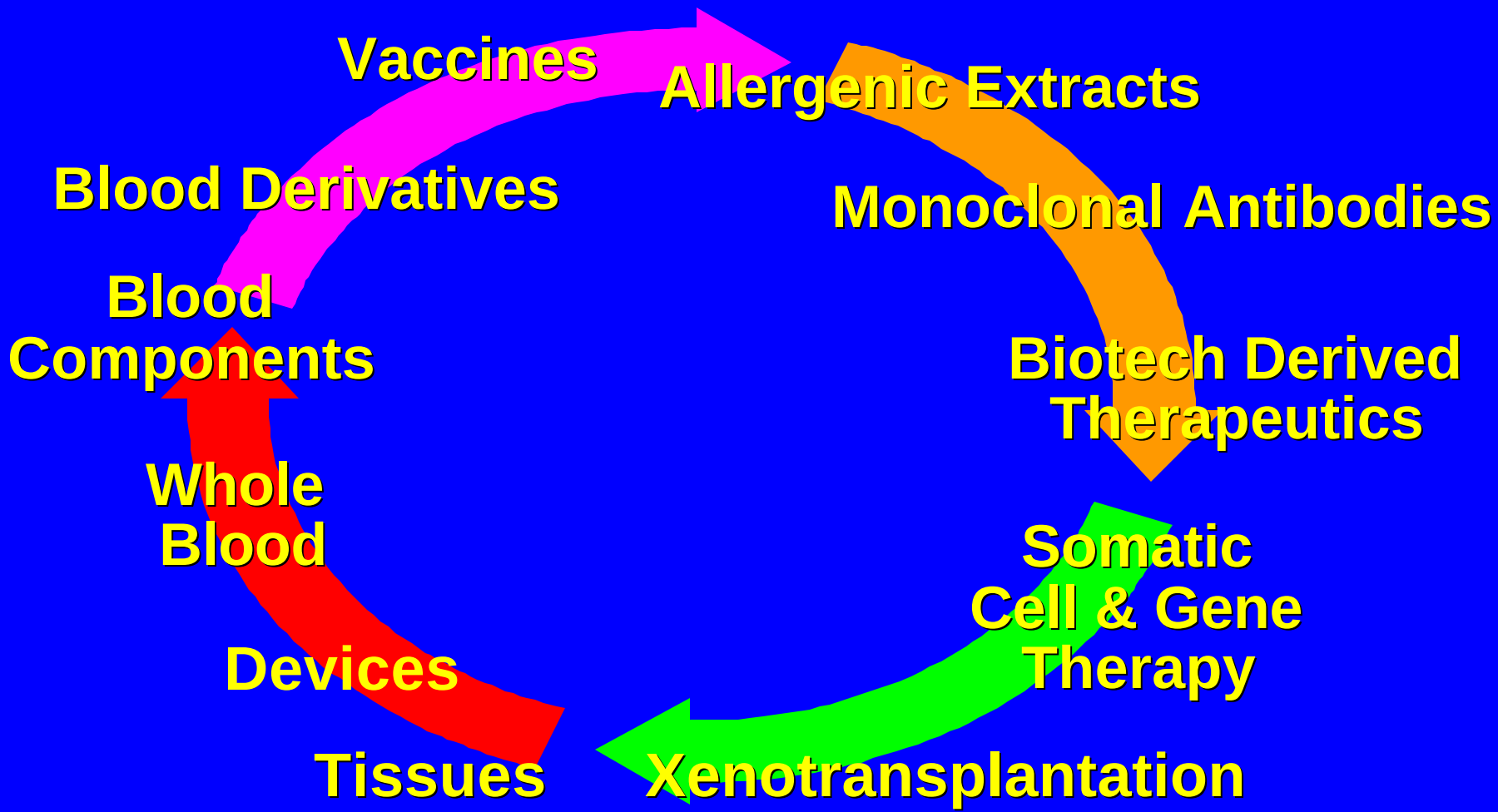
Standing Committee

- Scientific and technical experts
- Statistician
- Consumer representative
- Industry representative

Other invitees

- Patient representative (oncology, HIV, & …)
- Two experts in the particular disease or condition the product is intended to treat

BIOLOGICAL PRODUCTS REGULATED BY CBER



Types of Product Approval Issues

- Significant new products.
- Those with significant potential for risk compared to narrow therapeutic benefit.
- Those with controversial efficacy.
- Those under consideration for post-marketing studies.
- Those products which may be withdrawn from market because of safety or questionable efficacy.
- Other products issues in which the public expresses a significant interest.

Types of advice that we seek from our committees include:

- Recommendations regarding the design of clinical trials.
- Development of guidelines.
- Recommendations concerning post-marketing studies.
- Recommendations on whether the benefits of a new product outweigh the risks under the conditions in the proposed labeling.

TYPICAL AGENDA

(full day/one topic)

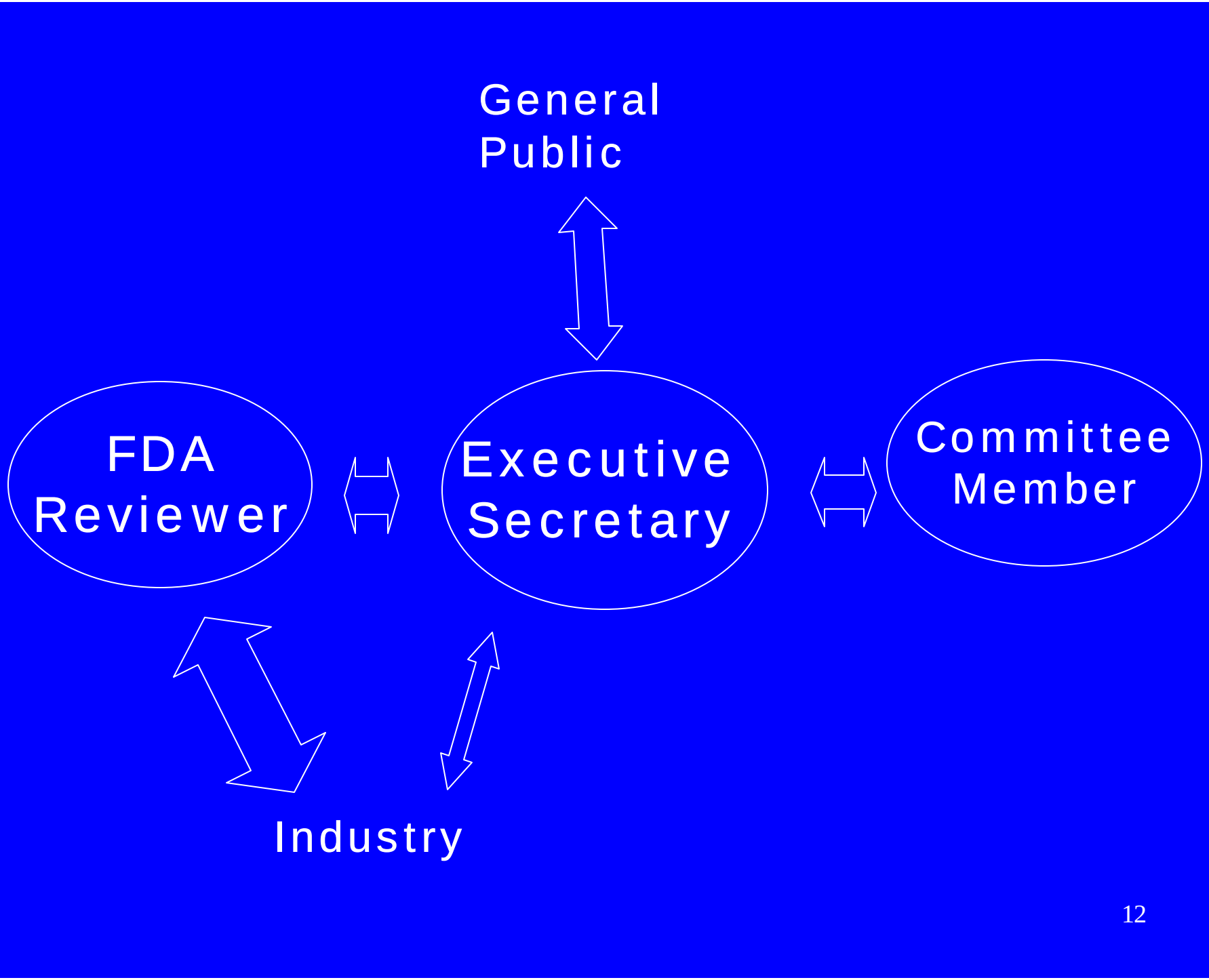
8:00 a.m.	Administrative remarks
8:15	FDA Introduction
8:30	Sponsor's Presentation
10:00	Break
10:15	FDA's Presentation
11: 45	Lunch
1:00 p.m.	Open Public Hearing
2:00	Committee Discussion & Vote
4:30	Adjourn

AC Meetings can contain "Closed Sessions"

- Reasons for a "closed session":
  - Discussion of trade secret or proprietary information
  - Internal agency documents if disclosure would impede agency action
  - Prevent invasion of personal privacy

“Not all advisory committee meetings are created equal”

- Learn as much about the committee as possible
- Work with the Committee’s Executive Secretary or Designated Federal Official


General Public
FDA Reviewer
Executive Secretary
Committee Member
Industry

Coordination with FDA for an Advisory Committee Meeting

- Maintain close communication
- Avoid surprises
- Make sure you understand all of our time lines
- Anticipate events

Interaction with the Public

- Every advisory committee meeting must have time designated for an open public hearing.
- Public must have access to briefing material, slides and handouts (they must be received in time to post on the web or they must be passed out at the meeting)

Members of Advisory Committees and Consultants are appointed Special Government Employees (SGEs)

SGEs are individuals who are employed full-time outside of the Government who may also be appointed by the government as an "employee" for intermittent or temporary service

Why Appoint as an SGE?

- SGEs must comply with criminal statutes regarding:
  - Conflict of Interest
  - Protection of Privileged Information

CBER Consultants

- CBER SACS maintains a list of approximately 300 CBER SGEs and their major area of expertise
- We often “borrow” SGEs from other Centers
- We also appoint new SGEs

Once Appointed an SGE can:

- Serve on a Committee as a member
- Serve as an ad hoc consultant for the Committee
- Can vote at the Committee Meeting
- Can attend a “Closed” Session
- Can do homework assignments
- Can participate in other types of FDA meetings

FDA Resources for Advisory Committees

- **CBER Advisory Committees Home Page -** http://www.fda.gov/cber/meeting.htm
  - **CBER AC Meeting dates, Committee Rosters and FR Notices**
- **FDA Dockets Management Home Page -** http://www.fda.gov/ohrms/dockets
  - **Meeting background material and transcripts**
- **AC Info line, 1-800-741-8138**
- **Executive Secretary**

Three factors that affect every AC meeting

- **Federal Statutes Governing Advisory Committees**
- Conflict of Interest
- Meeting Preparation

Statutory Reference

Federal Advisory Committee Act

(FACA)

Pub. L. 92-463, passed on October 5, 1972,

as amended September 13, 1976.

FACA

Through enactment of FACA the U.S. Congress sought to assure that the advisory committees:

- Provide advice that is relevant, objective and open to the public
- Comply with reasonable cost controls and record keeping requirements
- Under FACA the U.S. General Services Administration issues government-wide guidelines and regulations for advisory committee management

Three factors that affect every AC meeting

- Federal Statutes Governing Advisory Committees
- **Conflict of Interest**
- Meeting Preparation

Conflict of Interest

- A serious concern for the Agency and the public
- Advisory committee decisions must be impartial

Statutory COI Prohibitions

- An SGE may NOT participate in a particular matter if he/she has a direct or imputed financial interest that may be effected
- Effect must be direct and predictable and not speculative

Covered Relationships

- A person with which an SGE has or is seeking business
- A household member in a close personal relationship
- A person with which the SGE's spouse, parent or dependent child is serving or seeking to serve
- Any person for whom SGE has worked in the last year.
- Organizations in which SGE is an "active participant" such as serving as director or chair

COI Options

- Disclosure
- Waiver
- Limited Waiver
- Exclusion

Most Frequently used Waivers

(18 U. S. C. 208)

The appointing official determines:

- that the financial interest "is not so substantial as to be deemed likely to affect the integrity of the services"
- That the need for the individual's services outweighs the potential for a conflict of interest

Section 120 of the Food and Drug Modernization Act of 1997 (21U.S.C. S.355(n)(4))

- The SGE cannot review their own work (this criteria cannot be waived)

Three factors that affect every AC meeting

- Federal Statutes Governing Advisory Committees
- Conflict of Interest
- **Meeting Preparation**

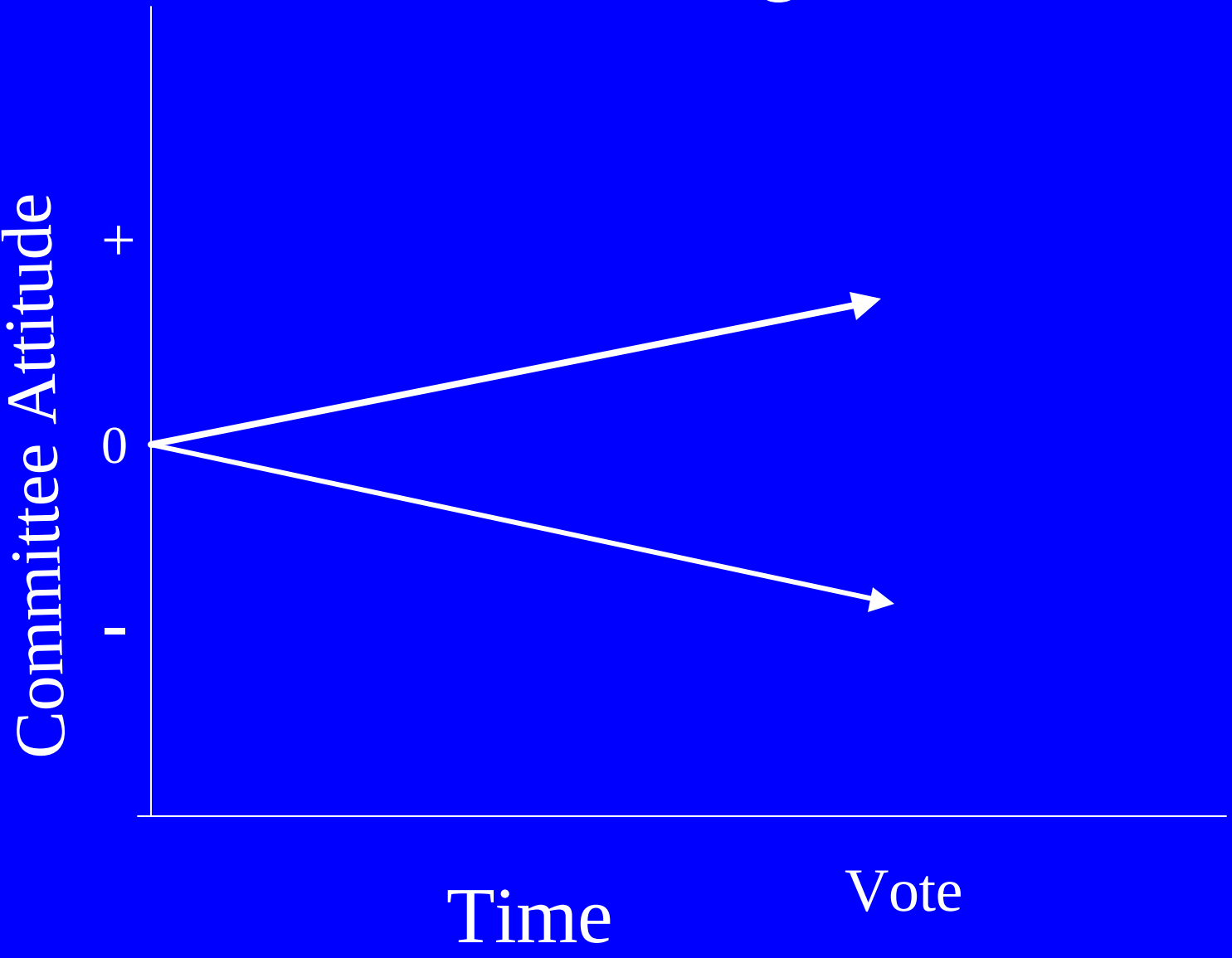
Preparation for an Advisory Committee Meeting

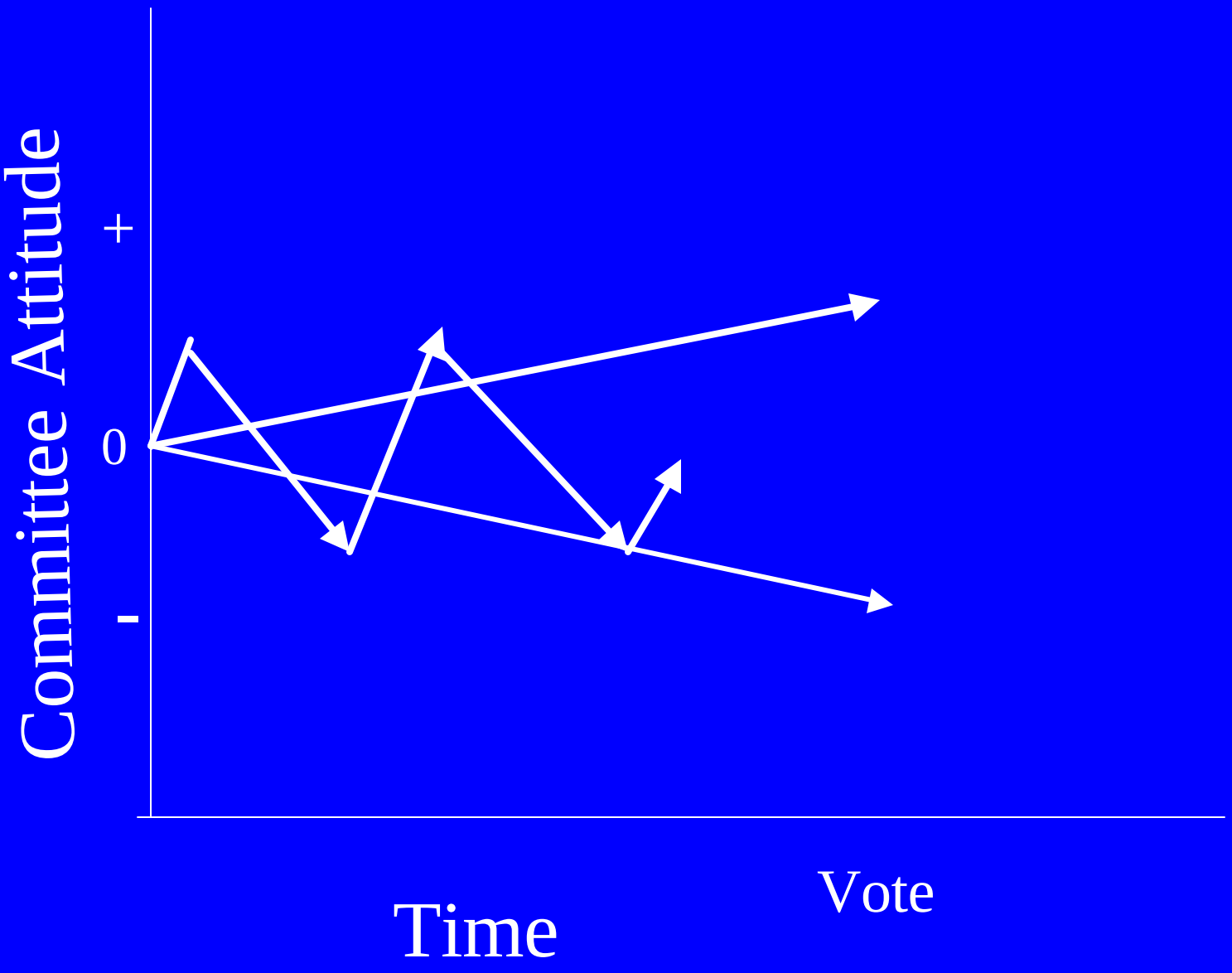
- Check CBER Home page for dates http://www.fda.gov/cber/advisory/advisory.html
- Contact Executive Secretary for meeting assistance and guidance as early in the planning phase as possible
- Familiarize yourself with CBER's Guidance for Industry Disclosing Information provided to Advisory Committees…….(Draft Guidance Feb 2001).

Preparation for an Advisory Committee Meeting (cont.)

- Ask who will serve as consultants and temporary voting members
- Develop Briefing Materials
- Know when the Federal Register Notice will be submitted and published

Possible Meeting Outcomes




Committee Attitude
+
0
-
Time
Vote

The job of a committee member is to evaluate the safety and efficacy of our products. They are to balance the **risks and benefits and** and provide FDA with advice that is in the public's best interest.

Remember

- When the gavel goes down, the meeting is over